US ERA ARCHIVE DOCUMENT

TECHNICAL SUPPORT SECTION EFFICACY REVIEW-1

Disinfectants Branch

$\int IN \frac{3-14-80}{4-4-80} OUT \frac{4-4-80}{4-4-80}$
William & Campbell or
Reviewed by William E. Campbell Jr. Date 4-4-80
EPA Reg. No. or File Symbol 10182-RO
EPA Petition or EUP No. 10182-EUP-11
Date Divison Received 2-14-80
Type Product(s): I, (D), H. F, N. R, S Swimming Pool
Data Accession No(s). 241791
Product Mgr. No. 32 Castillo
Product Name(s) Baquacil
Company Names(s) ICI Americas Inc.
Submission Purpose New Registration/New Chemical
Chemical & Formulation Liquid Concentrate
Product weight 8.816 lbs./gal.
Active Ingredient(s): %
poly(iminoimidocarbonyliminoimidocarbonyliminohexamethylene hydrochloride)20

200.0 Introduction

- 200.1 Use: A swimming pool water disinfectant and algicide.
- Background Information: An EUP was issued on December 4, 1978 to evaluate the product for the use indicated in 200.1 above. Efficacy data generated from trials at seven public swimming pools were submitted and found to be adequate to support efficacy of the product as a swimming pool water disinfectant. ICI Americas, however, intends to market the product primarily to homeowners and is concerned that the labeling be appropriate for such use. Therefore, an application for a one year extension of the subject EUP was submitted on February 21, 1980 (Efficacy review of 3/31/80) to evaluate labeling recommendations and/or supplemental chemical treatments.

201.0 Data Summary

- Data Summaries: The field test data contained in the submitted volume were summarized in our review of the second and fourth quarterly reports dated August 7, 1979 and February 11, 1980, respectively.
- Other Summarized Results: Under normal use conditions, a test kit would be used to determine the concentration of product in the pool water. Therefore, in our review of the fourth quarterly report of the Experimental Use Program, it was indicated that data must be provided, prior to registration to show the accuracy and precision of the test kit.

Results of tests to determine the reliability of the BAQUACIL test kit indicate that a modified procedure involving the use of BAQUACIL CHECK SOLUTION, to be used in conjunction with existing kit materials, offers advantages of accuracy and reliability in use over the original method that did not use a check solution.

In a study to evaluate the improved test kit method, 16 subjects were asked to use a BAQUACIL CHECK SOLUTION, (2000 ppm BAQUACIL) and the instructions to "titrate" concentrations of BAQUACIL in unknown samples. By this method, the 16 panelists were able to reliably estimate finite BAQUACIL concentrations with approximately 90% accuracy. Furthermore, test subjects found this method easier to use than the original method. The improved method provides a better color comparator and facilitates decisions concerning BAQUACIL concentrations of the unknown samples.

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - II Disinfectants Branch

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Product Manage	er No. 32 Castillo
Product Name	Baquacil
Company Name	ICI Americas Inc.

202.0 Conclusions and Recommendations

202.1 Claims Related to Human Health

202.1 Efficacy supported by the data: The efficacy data generated under the EUP together with the data submitted in support of the application for the EUP are considered adequate to support efficacy of the product as a swimming pool water disinfectant at a product concentration of 30-50 ppm.

202.2 Claims Not Related to Human Health

Pursuant to Section 3(c)(5) of the FIFRA, as amended by the Federal Pesticide Act of 1978, and under the provisions of 40 CFR 162.18-2, claims for control of microorganisms not directly related to human health do not require supporting efficacy data. On this basis, algicidal claims for the product do not require supporting efficacy data. Therefore, the algicidal and algistatic data contained in the submitted report are not summarized in this review.

203.0 Labeling

In our review of the fourth quarterly report, the following labeling comments were to be resolved prior to registration.

A. Effective Dosage Range

Based on data generated under the EUP, the lowest acceptable level of product in the pool water, before a top-up dose is required must be specified.

B. Compatibility

Since the recommendations for using most algicides and oxidizing agents in swimming pools are based on the compatibility of the chemicals with chlorine, appropriate precautionary wording against using commonly recommended algicides and/or oxidizing agents known to be incompatible with this product must be provided in labeling.

C. The meaning of compatibility shall also include consideration for the comfort of the pool user. Therefore, the parameters of alkalinity and/or hardness of pool water chemistry necessary for optimum bather comfort must be addressed in labeling.

These comments have been adequately addressed in the revised labeling.

Note: If conditional registration of this new active ingredient is considered, it should be noted that this review does not address the "public interest" provision of Section 3(c)(7)(C) of the FIFRA as amended.